REMARKS

Status of the Claims

Prior to entry of this response, claims 36-63 were pending in the present application and claims 58-60 were withdrawn from consideration.

Applicants' representatives note with appreciation the Examiner's withdrawal of the previously-imposed restriction requirement between groups I and II and acknowledge that claims 56 and 57 directed to group II are presently under examination together with the claims of group I.

By virtue of this response, claims 36, 37, 53, 54, 55, and 62 have been amended and claims 56-60 have been cancelled After entry of this amendment, claims 36-55 and 61-63 will be pending. No new matter has been added by the amended claims. Support for the claim amendments is provided in detail below.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Amendments to the Specification

The abstract of the disclosure, starting on page 93 of the present application, has been amended to conform to the word count limitations set forth in MPEP § 608.01(b). No new matter has been added by amendment to the abstract of the disclosure.

Amendments to the claims

Claim 36 has been amended by deletion of "for example" before the listed substituents. A voluntary amendment has also been made to claim 36 to delete "(I)" beneath the formula ii).

Claim 37 has been amended to delete reference to the substituent "R^{11}" which is not present in claimed formula ii).

Claim 53 has been amended to replace "characterized in that" with "wherein" as suggested by the examiner on page 4 of the Office Action.

Claim 54 has been amended to refer to a reaction mixture in order to provide sufficient antecedent basis for the reference to reaction mixture in claim 55.

Claim 55 has been amended to replace "characterized in that" with "wherein" and to delete the word "resulting."

Claim 62 has been amended to recite that the respiratory, urinary and/or gastrointestinal disease treated is a disease "in which the muscarinic M_3 receptor is implicated." Support for this amendment may be found in the application as filed, e.g., from page 27, line 19 to page 31, line 16.

Rejections under 35 U.S.C. § 112, first paragraph

Claim 62 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants respectfully traverse this rejection.

The test of enablement is that one reasonably skilled in the art could make or use the invention from the disclosures in the patent application coupled with information known in the art without undue experimentation. *See*, Manual of Patent Examining Procedures (MPEP), §2164.01. The enablement requirement does not extend to *every possible known disease*, as suggested by the Examiner. Rather, the use of a compound need be enabled such that one skilled in the art could practice the invention *without undue experimentation.*

Applicants note that the present application provides experimental evidence regarding the activity of the claimed compounds and that claim 62 as amended recites respiratory, urinary and/or gastrointestinal diseases in which the muscarinic M_3 receptor is implicated.

Applicants submit herewith a Declaration under 37 C.F.R. §1.132 signed by a Biological Programme Leader at Almirall Prodesfarma, Amadeu Gavaldà, describing the test procedures and

results obtained for compounds of the invention in human muscarinic receptor studies and in tests on bronchospasm in the guinea pig (*See also* spefication pages 27-29). These tests are used, and have in the past been used, to identify compounds which are useful in the treatment of respiratory, urinary and/or gastrointestinal diesease in which the muscarinic M_3 receptor is implicated. The claimed subject matter is clearly enabled.

Also submitted herewith, and in the accompanying Supplemental Information Disclosure Statement, is a literature reference (Eglen, R.M. et al. (October 1997). "Muscarinic Receptor Subtypes: Pharmacology and Therapeutic Potential," *DN&P* 10(8): 462-469) which also provides evidence of the known correlation between the biological activity demonstrated by the experimental procedures documented in the application as filed and the therapeutic utilities which Applicants have identified in the application and specifically, which Applicants have claimed in claim 62. Applicants note in particular the first two paragraphs on page 467 of the literature reference.

In light of the disclosures in the present application and information known in the art, one reasonably skilled in the art could use the invention of claim 62 without undue experimentation. Claim 62 as amended is enabled and Applicants respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph rejection of claim 62.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 36, 37, 53, 55, 57 and 62 are rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants individually address the 35 U.S.C. § 112, second paragraph rejection of each claim rejected under this section.

Claim 36 is rejected under 35 U.S.C. § 112, second paragraph for the recitation of the term "for example". In response, Applicants have deleted the term "for example" from claim 36.

Claim 37 is rejected under 35 U.S.C. § 112, second paragraph for the recitation of "R^{11}" because the term does not have antecedent basis. In response, Applicants have deleted "R^{11}" from claim 37 and note that "R^{11}" refers to substituents that are present in formula i), but not in formula ii), which is recited in claim 36.

Claim 53 is rejected under 35 U.S.C. § 112, second paragraph for recitation of the term "characterized in that." In response, Applicants have replaced the term "characterized in that" with the Examiner's suggested term "wherein." In addition, the section of the Office Action relating to the 35 U.S.C. § 112, second paragraph rejection of claim 53 states, "Also, the IC50 values are obtained in vivo or in vitro assay? What is meant by (Hm3)?" In response, Applicants note that the IC50 values can be obtained by the procedure described in the specification and in the accompanying Declaration and that Hm3 are human muscarinic M_3 receptors. The relevant disclosure in Applicants' specification regarding these points can be found, e.g., on page 27, lines 20-33 and page 29 lines 7-10. Lastly, the section of the Office Action relating to the 35 U.S.C. § 112, second paragraph rejection of claim 53 states that claim 53 should be deleted because it is directed to mechanism only and not any utility. However, claim 53 is not directed to a mechanism. Claim 53 is dependant on claim 36 and is directed to chemical compounds that have an IC50 value for muscarinic M3 receptors (Hm3) of less than 35nM. The IC50 value can be measured by the method described in the Applicants' specification. The utility of compounds exhibiting such activity is discussed throughout the subject application as filed.

Claim 55 is rejected under 35 U.S.C. § 112, second paragraph for recitation of the term "characterized in that." In response, Applicants have replaced the term "characterized in that" with the Examiner's suggested term "wherein." In addition, Applicants have amended claim 54 to refer to a reaction mixture in order to provide sufficient antecedent basis for the reference to reaction mixture in claim 55.

Claim 57 has been cancelled, rendering the rejection of claim 57 under 35 U.S.C. § 112, second paragraph moot.

Claim 62 is rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite because the terms respiratory disease, urinary disease and/or gastrointestinal disease are recited. In response, Applicants assert that one of skill in the art would readily recognize the specific conditions that are associated with a respiratory disease, urinary disease and/or gastrointestinal disease and that recitation of the terms does not render claim 62 indefinite. However, Applicants have specified in amended claim 62 that the respiratory, urinary and/or gastrointestinal disease is a disease "in which the muscarinic M3 receptor is implicated."

In view of the foregoing, Applicants respectfully request withdrawal of each of the 35 U.S.C. § 112, second paragraph rejections of claims 36, 37, 53, 55, 57 and 62.

Rejections under 35 U.S.C. § 102(a)

Claims 56 and 57 are rejected under 35 U.S.C. 102(a), as allegedly being anticipated by Gao (Chemical J. of Chinese universities). Claims 56 and 57 have been cancelled, rending the 35 U.S.C. 102(a) rejection of claims 56 and 57 moot.

Rejections under 35 U.S.C. § 102(b)

Claims 56 and 57 are rejected as allegedly anticipated by Noronha-Blob (Eur. J. Pharmacol.). Claims 56 and 57 have been cancelled, rendering the 35 U.S.C. 102(b) rejection of claims 56 and 57 moot.

Allowable Subject Matter

Applicants note that claims 38-52, 54, 61 and 63 are objected to for being dependant on rejected base claims. Applicants also acknowledge with appreciation the Examiner's indication that claims 38-52, 54, 61 and 63 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants submit that the rejected base claims from which claims 38-52, 54, 61 and 63 depend are in immediate condition for allowance.

Accordingly, Applicants submit that dependant claims 38-52, 54, 61 and 63 are also in condition for immediate allowance and respectfully request withdrawal of the objection to claims 38-52, 54, 61 and 63.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 251502007410. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By _____

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